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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,783	04/26/2002	Satoshi Mori	SAE-005	7671

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EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,783	MORI ET AL.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are pending and are examined.

Drawings

The drawings of 01/04/2002 are objected to because the sequences of Figures 9 and 10 span on multiple pages, and the Figures are labeled as Fig. 9 and Fig. 10, respectively instead of Figs. 9A-9D and Figs.10A-10G. Appropriate correction is required.

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and amino acid sequences set forth in 37 CFR1.821 (a)(1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

The CRF and paper sequence listings of 01/30/2002 have been entered. However, the sequences of Figures 9-10, and 13-14 have not been identified by SEQ ID NO: in the Brief Description of the Drawings on page 8 of the specification. Applicant is respectfully requested to identify the sequence presented in the figures or to submit a new Sequence Listing which comprises said sequences. Also, the sequences on pages 25-27 have not been identified by SEQ ID NO: Applicant is respectfully requested to identify the sequences on pages 25-27 or to submit a new Sequence Listing which comprises said sequences. Applicant is also required to amend the specification to insert SEQ ID NO: for said sequences.

Claim Objections

Claims 1 and 5 are objected to because what is intended by "genome gene" and "barley genome *naat*" is unclear. This implies that there are non-genome genes. The word "gene" inherently implies genomic DNA comprising all regulatory regions. It is suggested that "genome" be deleted from claim 1; and "genome is barley genome naat" be replaced with ---gene is a barley *naat* ---

At claims 2-6, "A" should be changed to ---The--- for proper dependency.

Claim 6 is objected for including two periods. A claim cannot recite more than one period. Appropriate correction is required. Also, a gene does not generate protein; a gene encodes a protein.

Claim 7 is objected to because a plant cannot be manufactured. It is suggested that "manufactured" be replaced with ----produced----.

Claim 8 is objected to because "The seeds of gramineae" lacks the proper article. It is suggested that "The seeds" be replaced with ----Seed of the gramineae----.

Claim 9 is objected to because "The cells of gramineae " lacks proper article. It is suggested that "The cells" be replaced with ----Cells of the gramineae----.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for failing to recite complete method steps that result production of a plant. The preamble recites producing gramineae, but the last method step does not result in a plant. The gene is introduced into what?

Claim 3 is indefinite in the recitation of "wherein a promoter used is CaMV35S because claim 1 does not recite the use of a promoter . Appropriate correction is required to more clearly define the metes and bounds of the claim.

Claim 6 is indefinite for failing to recite specific hybridization conditions required for Applicant's stringency conditions. There are many different ways to define "stringency", and the specification fails to describe "stringent conditions". Absent specific hybridization and wash conditions, one would not know the metes and bounds of the claim. Dependent claims 7-10 don't obviate the rejection.

Claim 6 is indefinite because according to the sequence listing SEQ ID NO: 1 defines protein sequence rather than nucleotide sequence.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. The claims do not read "transformed seed" and "transformed cells". The seed and cells of a transgenic plant may not contain the transgene of the parent plant, due to chimerism. If the seed/cells do not contain the transgene, then the claims will read on the product of nature. It is suggested that the claims are amended to read ---Transformed seed--- and ---Transformed cells----.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a method for producing a gramineae comprising introducing into the plant a gene encoding SEQ ID NO: 1 or 2, and a transformed gramineae plant produced by said method, and transformed seed and cells from said gramineae. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for manufacturing a gramineae with iron deficiency resistance, the method comprising transforming a gramineae plant with a gene that codes for any enzyme in the biosynthetic pathway of mugineic acids including nicotianamine amino transferase (NAAT) encoding genes from any source and those that hybridize to SEQ ID NO:1 (note SEQ ID NO:1 is listed as a protein sequence in the sequence listing) under any stringency conditions including any low , moderate, and high stringency conditions. The claims are also drawn to transformed gramineae, cells and seed thereof and a method for growing said transformed Gramineae plant in an iron deficient field.

Applicant teaches a method for producing gramineae plant by transforming the plant with a barley gene encoding SEQ ID NO: 1 or 2, and transformed gramineae

plants/cells and seeds with iron deficiency resistance (as defined in the specification). Applicant also teaches isolation of NAAT gene from barley (SEQ ID NO:3). Applicant teaches that the barley NAAT gene contains six introns and seven exons (Example 6; note sequence listing shows only a single barley gene; SEQ ID NO:3) Applicant also teaches analysis of iron deficiency resistance in barley transformed with barley NAAT gene/cDNA (Examples 1-8).

Applicant has not taught transformation of a gramineae with genes other than SEQ ID NO: 3 nor that Applicant provided guidance for how to identify and obtain other genes in the biosynthetic pathway of mugineic acids including genes encoding NAAT from non-barley sources. The instant specification fails to provide guidance regarding all other genes encoding enzymes involved in the mugineic biosynthesis pathways in different species, which genes may yet have to be discovered/identified. An article by Ma et al from the Journal of Experimental Botany (Vol. 50, No. 334, pp. 723-726 (1999) Applicant's IDS) discusses variation in mugineic acid biosynthetic pathway in gramineae. Ma et al specifically address variation in mugineic acid biosynthetic pathway in wheat and state "(t)he biosynthesis of phytosiderophores is induced by Fe-deficiency and kind and number of biosynthetic phytosiderophores biosynthesized differ among different species and cultivars among graminnaceous plants. Although there have been extensive physiological and biological studies of the biosynthesis of phytosiderophores, few species have been analyzed". The cited reference further states "...the genetic control of the biosynthesis of different phytosiderophores is poorly understood". Therefore, it is apparent that further research considered undue is required before one

skilled in the art would be able to use any gene in the biosynthesis of mugineic acid to induce iron deficiency resistance in a plant. Furthermore, Applicant has provided no evidence that suggests all genes encoding enzymes involved in the mugineic acid biosynthetic pathway are capable of inducing iron deficiency resistance in susceptible gramineae.

The state of the art for isolating genes with specified function is highly unpredictable. Substantial guidance is required with respect to hybridization/wash conditions that would allow the specific isolation of the target genes. In the absence of such guidance, one skilled in the art has to proceed with trial and error experimentation to screen through the vast number of cDNA and genomic clones to identify those genes encoding enzymes in the biosynthetic pathway of mugineic acids, and to evaluate the ability of said genes to increase resistance against iron deficiency in any gramineae plant. Applicant would also have to evaluate the ability of said transformed plant to grow in iron deficient field. Applicant has not provided guidance for regions in the full-length sequence of SEQ ID NO: 3 which have the ability to encode a functional enzyme and regions which would tolerate modifications.

Therefore, given the lack of sufficient guidance in the specification; the limited working examples; the nature of the invention; the state of the art and unpredictability as discussed above, the claimed invention is not enabled throughout the broad scope. See, *In re Wands (858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).*

Written Description

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method for manufacturing a gramineae with iron deficiency resistance, the method comprising transforming a gramineae plant with a gene that codes for any enzyme in the biosynthetic pathway of mugineic acids including nicotianamine amino transferase (NAAT) encoding genes from any source and those that hybridize to SEQ ID NO:1 (note SEQ ID NO:1 is listed as a protein sequence in the sequence listing) under any stringency conditions including low , moderate, and high stringency conditions. The claims are also drawn to transformed gramineae, cells and seed thereof and a method for growing said transformed Gramineae plant in an iron deficient field.

The claimed invention is not adequately described because all the genes encoding enzymes involved in the biosynthesis of mugineic acid that are required for the production of plants with iron-deficiency resistance are not described in the specification. In *Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), the court stated:

> An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention... Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404).

The court held that held that human insulin-encoding cDNA is not described by prophetic example, which sets forth only a general method for obtaining the human cDNA:

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity...Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes...does not necessarily describe the DNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA....Accordingly, the specification does not provide a written description of human cDNA (43 USPQ2d at 1405).

The description of a single species of rat cDNA was held insufficient to describe the broad genera of vertebrate or mammalian insulin:

"In claims to genetic material...a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It doesn't define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function...does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (43 USPQ2d at 1406).

The court continued:

"Thus...a cDNA is not defined by the mere name 'cDNA', even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA...A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". (43 USPQ2d at 1406). See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The *University of Rochester v. G.D. Searle* & Co., Inc.(, U.S. District Court, Western District of New York, Decision and Order No. 00-CV-6161L,) decided 05 March 2003, at page 8, bottom paragraph, that method claims are properly subjected to a written description requirement if the starting material which requires that method is itself inadequately described. The court specifically stated, "(T)he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment. It means little to "invent" a method if one does not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real;..... and there is no meaningful possession of the method."

Applicant has not described the composition and structure of all genes encoding enzymes involved in the biosynthesis of mugineic acid including genes encoding NAAT from non-barley sources, and all genes that the hybridize to the disclosed sequence under any low, moderate and high stringency conditions. The stringency conditions of claim 6 will not yield nucleic acid molecules that are structurally and functionally related to the disclosed sequence encoding SEQ ID NO:1 or 2 . In addition, Applicant has not described structural elements common to all genes encoding enzymes involved in the biosynthesis of mugineic acid including genes encoding NAAT encoding genes. Applicant has not described a representative number of genes involved in MA biosynthesis, and a literature review does not indicate that the genes are well known. Consequently, the claimed method for producing gramineae and transformed plants

produced by said method, and a methods for using said transformed plants are not adequately described. Since Applicant has not described the nucleic acid molecules of the claimed invention, host cells and plant cells/ seed/plant parts/progeny comprising said nucleic acid molecules are similarly not described.

Therefore, the claimed invention does not meet the current written description requirements. See, also, the Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-9 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Satoshi et al (EP0860499 A2, Applicant's IDS).

The claims are broadly drawn to a method for manufacturing a gramineae with iron deficiency resistance, the method comprising transforming a gramineae plant with a gene that codes for any enzyme in the biosynthetic pathway of mugineic acids including any nicotianamine amino transferase (NAAT) encoding gene from any source or that hybridizes to SEQ ID NO:1 (note SEQ ID NO:1 is listed as a protein sequence in the sequence listing) under any stringency conditions including any low , moderate, and high stringency conditions. The claims are also drawn to transformed gramineae, cells

and seed thereof and a method for growing said transformed gramineae plant in an iron deficient field.

Satoshi et al teach a method that employs a gene from barley encoding NAAT having 100% sequence identity to Applicant's SEQ ID NO: 1 or 2 for transformation of a gramineae plant. The method comprises introducing into the plant an expression vector comprising the gene operably linked to CaMV35S promoter. On page 4, lines 44-58, the cited reference teaches that expression of NAAT gene in the plant is induced by iron deficiency conditions and induces increased uptake of insoluble iron from the soil by the plant. The cited reference further teaches a transformed gramineae having resistance iron-deficiency, and cells and seed thereof expressing NAAT for use in iron-deficiency field (see at least the Abstract). Transformed plants produced by said method will inherently grow in iron deficiency field.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori Satoshi (Soil Sc. Plant Nutr, Vol. 43, pp. 975-980, 1997, Applicant's IDS).

The claims are broadly drawn to a method for manufacturing a gramineae with iron deficiency resistance, the method comprising transforming a Gramineae plant with a gene that codes for any enzyme in the biosynthetic pathway of mugineic acids including nicotianamine amino transferase (NAAT) encoding genes from any source and those that hybridize to SEQ ID NO:1 (note SEQ ID NO:1 is listed as a protein sequence in the sequence listing) under any stringency conditions including any low , moderate, and high stringency conditions. The claims are also drawn to transformed gramineae, cells and seed thereof and a method for growing said transformed Gramineae plant in an iron deficient field.

Mori teaches a method for isolating a gene encoding NAAT from barley which gene is induced by iron deficiency. Mori suggests transformation of gramineae plants with said gene for iron deficiency resistance so that plants can be grown in iron deficiency conditions (see the whole document).

It would have been obvious to one of ordinary skill in the art at the time the application was filed to transform any gramineae plant including rice, barley and maize with a NAAT gene as suggested by Mori with a reasonable expectation of success. One

would have been motivated to do so because majority of important cereal crops including rice are known to be susceptible to iron deficiency. While Mori does not explicitly teach use of CaMV 35 S with the barley NAAT gene, the use of CaMV 35 S promoter in plant transformation methods was known before Applicant's invention. Transformation of plants including gramineae with a desired gene is well known in the art. One of ordinary skill in the art can readily transform any monocot plant with any desired without any unexpected results. Applicant's unexpected results are limited to the transformation of a gramineae with SEQ ID NO: 3, transformed plants produced from said method, transformed cells and seed of said plants. Therefore, the claimed invention as whole was *a prima facie* obvious.

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/20/04
Mai

Medina A. Ibrahim

MEDINA A. IBRAHIM
PATENT EXAMINER

1638